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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,641	01/18/2002	Chieh-Sheng Lin	P1393	3585

7590 04/03/2003

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/053,641		LIN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Daniel M Sullivan		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

This Office Action is a response to the "Response to Office Action" filed 30 January 2003 (Paper No. 9) in reply to the Non-Final Office Action mailed 30 July 2003 (Paper No. 6). Claims 1-32 were considered in Paper No. 6. Claims 2-32 were canceled in Paper No. 9. Claim 1 is pending and under consideration herein.

#### ***Response to Amendment***

All objection to and rejection of claims 2-32 is rendered moot by cancellation of the claims.

#### **Drawings**

The formal drawings filed 30 January 2003 are approved.

#### **Specification**

Objection to the specification is withdrawn in view of the amendment thereto in Paper No. 9.

#### **Claim Rejections - 35 USC § 102**

Rejection of claim 1 under 35 U.S.C. 102(b) as anticipated by Houdebine et al. (1999; U.S. Patent No. 5,965,788) is withdrawn in view of the amendment of the claim in Paper No. 9.

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Claim Rejections - 35 USC § 103

Claim 1 stands rejected under 35 U.S.C. 103(a) as unpatentable over Houdebine and in further view of Bleck et al (1993; WO 93/04165) for reasons of record in Paper No. 6 and herein below in the response to arguments.

Rejection of claim 1 under 35 U.S.C. 103(a) as unpatentable over Yoo et al. (2000; WO 00/15808) in view of Liersch et al. (1995; 5,422,249) is withdrawn in view of the amendment of the claim in Paper No. 9.

Rejection of claim 1 under 35 U.S.C. 103(a) as unpatentable over Johnson (1998; WO 98/35689) in view of Liersch is withdrawn in view of the arguments of record in Paper No. 9.

***Response to Arguments***

In response to the rejection of claim 1 under 35 U.S.C. 103(a) as unpatentable over Houdebine and in further view of Bleck et al., Applicant argues that the combination of teachings would not have been obvious because Houdebine does not express dissatisfaction with the WAP promoter. Applicant asserts that the reliance of Houdebine on the rabbit WAP promoter would teach away from selecting another promoter for protein expression in a transgenic animal.

This argument has been fully considered but is not found persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

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*Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's response does not address the motivation to combine the teachings set forth in the previous Office Action, which comes from Bleck *et al.* Bleck *et al.* explicitly teaches that the  $\alpha$ -lactoalbumin promoter is preferred over other mammary specific promoters for the purpose of expressing proteins in mammary glands because it exerts the tightest lactational control of all milk proteins, it is independently regulated from other milk proteins and is produced in large quantity by lactating animals. In contrast, Houdebine does not provide any explicit teaching that would dissuade the skilled artisan from substituting the  $\alpha$ -lactoalbumin promoter of Bleck for the WAP promoter for the purpose of obtaining the tightest lactational control and highest production of hirudin. Therefore, the claimed invention as a whole would have been obvious to the ordinary skilled artisan at the time the instant application was filed based on the combined teachings of Houdebine and Bleck *et al.*

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

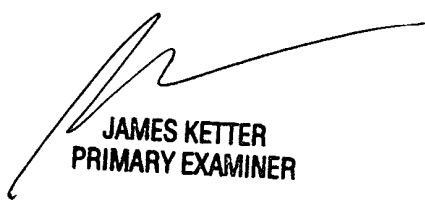
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms  
March 31, 2003



JAMES KETTER  
PRIMARY EXAMINER